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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/648,270	05/15/96	TOR	Y A-63463-1

EXAMINER

HM22/0119

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CRANE, I ART UNIT	PAPER NUMBER
1623	16

DATE MAILED: 01/19/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 12/23/98 (Amdt C) -----

☒ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-3, 6-8, 11, 14-16 & 26-43 ----- is/are pending in the application.
Of the above, claim(s) 1-3, 6-8, 11 and 14-16 ----- is/are withdrawn from consideration.
☐ Claim(s) ----- is/are allowed.
☒ Claim(s) 26-43 ----- is/are rejected.
☐ Claim(s) ----- is/are objected to.
☐ Claim(s) ----- are subject to restriction or election requirement.

☒ Claims ~~XX~~ 4-5, 9-10 and 12-13 have been cancelled.
Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on ----- is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on ----- is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.
☐ received in Application No. (Series Code/Serial Number) -----
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: -----

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). -----
☐ Interview Summary, PTO-413
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

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-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

Art Unit 1623

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group 1600, Art Unit 1623.

- 5 Claims **4-5, 9-10, 12-13 and 17-25** have been cancelled and new claims **26-43** were added as per the preliminary amendments filed December 23, 1998.

Claims **1-3, 6-8, 11, 14-16 and 26-43** remain in the case.

- 10 Claims **1-3, 6-8, 11 and 14-16** remain withdrawn from further consideration by the examiner, 37 C.F.R. §1.142(b), as being drawn to a non-elected invention. Election was made **without** traverse in Paper No. *R*

- 15 Note to applicant: Compound claims may be structured in a number of different ways. Examiner has seen many pharmaceutical firms present highly detailed and complete independent compound claims which include all of the variable definitions supported by the disclosure. A patent which illustrates this approach has been cited herein and a copy provided to present applicant with an example of how a detailed compound claim may be structured together with
20 more narrowly structured dependent claims. The rejections herein under 35 U.S.C. §112 would be greatly simplified or possibly eliminated if this approach to claim drafting were adopted by applicant.

- 25 Claims **26-43** are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and

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distinctly claim the subject matter which applicant regards as the invention.

In claim 26, line 6, the term

5 " A and B are selected from carbon or nitrogen, Y is a bond, and " is superfluous and may be deleted without changing the scope of the instant claim in any way.

10 In claim 26, line 7, the term "selected from the group consisting of acetylene, alkene, azo or imine" is incorrect because the Markush group is incorrectly formulated and the members of the group incorrectly presented. The instant term may be replaced with the term -- selected from the group consisting of α,β -diradical derived from acetylene, an alkene, azo [or] and imine --. The problem with this replacement is that the undefined "alkene" and "imine" substituents continue to render the noted term indefinite.

15 In claim 26, line 8, the term

"X and X₁ are co-ligands and wherein at least one of X and X₁ is present."
is indefinite because the chemical identities of the noted "ligands" is not further defined (Markush group in the specification?) in the
20 instant claim in chemical terms thereby rendering the scope of the instant claim indefinite. This same problem reoccurs in claim 27.

25 In claim 26, lines 9-10, the terms "alkyl", "substituted alkyl", "aromatic group" and "substituted aromatic group" are each lacking in a definite upper limit, and where the term "substituted" is present also are additionally indefinite because the instant claim fails to provide any guidance to permit the ordinary practitioner to determine which "alkyl", "aromatic" or "substituent" moieties may be present,

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or may not be present, within the scope of the noted terms (metes and bounds not adequately defined). This same problem reoccurs in claim 27.

5 In claim 28, the Markush group is grammatically and technically incorrect because the substituent moieties must by definition must be -- radicals derived from -- and are typically claimed in the singular (e.g. -- a nucleosidyl moiety -- or -- a nucleosidyl radical --) to make certain that there is no confusion concerning the possibility of multiple moieties being present
10 where only a single substituent moiety is intended. The instant Markush group therefore also appears to render the instant claim lacking in proper antecedent basis in claims 26 and 27. (See Note to applicant; this kind of Markush group should be in the first independent claim to avoid this problem). The problem reoccur sin
15 claims 29-30, 32-33, 35-36, 38-39, and 41-42.

In claim 28, lines 1-3, the term "substituted aromatic group" contains a technical term of art, "aromatic" which requires the presence of a functional group which contains a cyclic double bonded structure which obeys the Hückel " $4n+2$ " Rule (e.g. substituted
20 benzenes are included, $n = 1, 6 \pi$ -electrons). The noted term is inconsistent definitionally with subsequent terms in the instant claim. Terms included within the Markush group including "carbohydrates" and "lipids" are generic classes of substances which are not typically defined or thought by the ordinary practitioner to include any rings
25 which obey Hückels Rule. (See Note to applicant; this kind of Markush group should be in the first independent claim to avoid this problem).

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In claims **31, 34, 37 and 40**, the Markush group members are not properly presented. The noted terms should be replaced by --adeninyl--, -- guaninyl --, --thyminyl--, -- cytosinyl -- and -- uracilyl --, so that the incorrect use of chemical names of specific compounds are replaced with the names of radical substituents derived therefrom.

In claims **30, 33, 36 and 39** the subject matter of the instant claims is indefinite because the attachment point or points have not been defined. A similar problem occurs in claims **41-42**.

Claims **26-43** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In claims **26-43** the subject matter is directed to a vast array of substituent moieties (see Markush group in claim **28** the meanings of which is imputed to be included within claims **26-27**) but applicant's disclosure is limited in its specific embodiments to substituted nucleosides, substituted nucleotides, and substituted nucleoside phosphoramidites and nucleic acid sequences including a substituted nucleoside.

Claim(s) **26-43** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Claims 26-43 are broadly descriptive of the claimed invention, but the specific embodiments teach with a very small number of example how the instant invention may be carried out so as to incorporate the instant claimed compounds into an oligonucleotide.

5 For this reason the remaining exemplifications suggested by the instant claims 26-28 are deemed to represent subject matter which would require undue experimentation by the ordinary practitioner to reduce same to practice. It is well known and established that "law
10 requires that disclosure in an application shall inform those skilled in the art how to use appellant's alleged discovery, not how to find out how to use it for themselves." *In re Gardner et al.*, 166 USPQ 138 (CCPA 1970).

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See
15 MPEP 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. §1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS
20 FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY
25 EXTENSION FEE PURSUANT TO 37 C.F.R. §1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR

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RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

References made of record but not cited above are deemed to be either equivalents to the cited references or to be of interest as closely related prior art which shows the state of the relevant prior art.

Papers related to this application may be submitted to Group 1600 via facsimile transmission(FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone numbers for the FAX machines now operated by Group 1600 are **(703) 308-4556 and (703) 305-3592** for Official documents. Before transmission of any Draft communications, Applicant is respectfully requested to seek instructions from instant Examiner.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is 703-**308-4639**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marian Knode, can be reached at (703)-308-1235.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is 703-**308-1235**.

LECrane:lec
1/8/99

Marian C. Knode
MARIAN C. KNODE
SUPERVISORY PATENT EXAMINER
GROUP 1600